

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Boyle et al.

Serial No.: 08/974,186

Group Art Unit No.: 1632

Filed: November 18, 1997

Examiner: Campell, B.

For: Osteoprotegerin

Docket No.: A-378D5C



#13

**AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This is in response to the Notice to Comply with Sequence Rules as set forth in 37 CFR §§ 1.821 - 1.825, dated November 3, 1999.

The Applicants hereby request amendment of the specification as follows:

Pursuant to 37 CFR § 1.821 (d), please amend the description as follows:

- At p. 15, line 18: before "(rat)" insert -- 2 -- /  
At p. 15, line 18: before "(mouse)" insert -- 4 -- /  
At p. 15, line 19: before "(human)" insert -- 6 -- /  
At p. 23, line 25: after "3" insert -- (SEQ ID NO: 7) -- /  
At p. 24, line 1: after "3" insert -- (SEQ ID NO: 8) -- /  
At p. 24, line 2: after "5" insert -- (SEQ ID NO: 9) -- /  
At p. 25, line 4: after "3" insert -- (SEQ ID NO: 10) -- /  
At p. 25, line 5: after "3" insert -- (SEQ ID NO: 11) -- /  
At p. 25, line 19: after "3'" insert -- (SEQ ID NO: 12) -- /  
At p. 26, line 18: after "3" insert -- (SEQ ID NO: 13) -- /  
At p. 26, line 19: after "3" insert -- (SEQ ID NO: 14) -- /  
At p. 29, line 33: after "3" insert -- (SEQ ID NO: 15) -- /  
At p. 29, line 34: after "3" insert -- (SEQ ID NO: 16) -- /  
At p. 30, line 34: after "3" insert -- (SEQ ID NO: 17) -- /

entered 9W 2/20/01

**CERTIFICATE OF MAILING**

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March 7, 2000

Date

D. Zayler  
Signature

At p. 30, line 35: after "3" insert -- (SEQ ID NO: 18) -- /  
At p. 35, line 29: after "3" insert -- (SEQ ID NO: 19) -- /  
At p. 35, line 30: after "3" insert -- (SEQ ID NO: 20) -- /  
At p. 35, line 32: after "3" insert -- (SEQ ID NO: 21) -- /  
At p. 35, line 33: after "3" insert -- (SEQ ID NO: 22) -- /  
At p. 35, line 35: after "3" insert -- (SEQ ID NO: 23) -- /  
At p. 35, line 36: after "3" insert -- (SEQ ID NO: 24) -- /  
At p. 36, line 26: after "3" insert -- (SEQ ID NO: 25) -- /  
At p. 36, line 27: after "3" insert -- (SEQ ID NO: 26) -- /  
At p. 36, line 34: after "3" insert -- (SEQ ID NO: 27) -- /  
At p. 36, line 35: after "3" insert -- (SEQ ID NO: 28) -- /  
At p. 37, line 6: after "3" insert -- (SEQ ID NO: 29) -- /  
At p. 37, line 7: after "3" insert -- (SEQ ID NO: 30) -- /  
At p. 38, line 7: after "3" insert -- (SEQ ID NO: 31) -- /  
At p. 38, line 8: after "3" insert -- (SEQ ID NO: 32) -- /  
At p. 38, line 11: after "3" insert -- (SEQ ID NO: 33) -- /  
At p. 38, line 12: after "3" insert -- (SEQ ID NO: 34) -- /  
At p. 39, line 28: after "cycles" insert -- (SEQ ID NO: 35) -- /  
At p. 41, line 28: after "3" insert -- (SEQ ID NO: 36) -- /  
At p. 41, line 31: after "3" insert -- (SEQ ID NO: 37) -- /  
At p. 41, line 35: after "3" insert -- (SEQ ID NO: 38) -- /  
At p. 42, line 3: after "3" insert -- (SEQ ID NO: 39) -- /  
At p. 44, line 23: after "cycles" insert -- (SEQ ID NO: 40) -- /

In the claims

At p. 46, line 9: after "ID NO:" insert -- 2 -- /  
At p. 46, line 9: after "9A SEQ ID NO:" insert -- 4 -- /  
At p. 46, line 9: after "9B SEQ ID NO:" insert -- 6 -- /  
At p. 46, line 13: after "2B SEQ ID NO:" insert -- 1 -- /  
At p. 46, line 14: after "9A SEQ ID NO:" insert -- 3 -- /  
At p. 46, line 14: after "9B SEQ ID NO:" insert -- 5 -- /  
At p. 46, line 35: after "2B SEQ ID NO:" insert -- 1 -- /  
At p. 46, line 35: after "9A SEQ ID NO:" insert -- 3 -- /  
At p. 46, line 36: after "9B SEQ ID NO:" insert -- 5 -- /  
At p. 47, line 10: after "9B SEQ ID NO:" insert -- 5 -- /  
At p. 48, line 22: after "2B SEQ ID NO:" insert -- 2 -- /  
At p. 48, line 23: after "9A SEQ ID NO:" insert -- 4 -- /  
At p. 48, line 24: after "9B SEQ ID NO:" insert -- 6 -- /

At p. 48, line 31: after "9B SEQ ID NO:" insert -- 6 --

*In the Figures*

- In Figure 1A, after "SWHTS" insert -- (SEQ ID NO: 41)--
- In Figure 1A, after "LCAPL" insert -- (SEQ ID NO: 42)--
- In Figure 1B, after "TDSWH" insert -- (SEQ ID NO: 43)--
- In Figure 1B, after "TDDWH" insert -- (SEQ ID NO: 44)--
- In Figure 2C, after "219" insert -- (SEQ ID NO: 45)--
- In Figure 2C, after "280" insert -- (SEQ ID NO: 46)--
- In Figure 2C, after "207" insert -- (SEQ ID NO: 47)--
- In Figure 2C, after "227" insert -- (SEQ ID NO: 48)--
- In Figure 2C, after "197" insert -- (SEQ ID NO: 49)--
- In Figure 2C, after "224" insert -- (SEQ ID NO: 50)--
- In Figure 2C, after "202" insert -- (SEQ ID NO: 51)--
- In Figure 2C, after "191" insert -- (SEQ ID NO: 52)--

Please charge any fees associated herewith to Deposit Account 01-0519 and consider this a petition therefore if appropriate.

*Respectfully submitted,*

*[Handwritten signature]*  
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Date: March 7, 2000

Please send all future correspondence to:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Boyle et al.

Serial No.: 08/974,186

Filed: November 18, 1997

For: OSTEOPROTEGERIN

Docket No.: A-378D5C



Group Art Unit No.: 1632

Examiner: Campell, B.

RESPONSE TO OFFICE ACTION

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This is in response to the Office Action dated November 3, 1999 in which Claims 49-53 are rejected under 35 U.S.C. 112. Reconsideration and withdrawal of the rejection are requested in view of the remarks set forth below.

## REMARKS

Claims 49-53 are currently pending in the application and are directed to a method of regulating osteoprotegerin (OPG) levels comprising modifying an animal with a nucleic acid encoding OPG.

The Examiner has noted that the application fails to comply with the requirements for disclosure of nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 through 1.825. In order to bring the application into compliance, an amendment inserting sequence identifiers into the specification is attached hereto.

Claims 49-53 are rejected under 35 U.S.C. 112, first paragraph, as the subject matter was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

The Examiner argues that the claims are to be construed as treatment method claims because the specification allegedly does not specify any purpose for regulating OPG other than for treatment. On this basis, the previous grounds of rejection as forth in paper 4, p. 2-4 and paper 8, p.2 are maintained.

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March 7, 2000

Date

A handwritten signature in black ink that reads "D. Taylor".

Signature